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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,613	07/23/2004	Vladimir Khripach		4612

7590 07/06/2005

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EXAMINER
HARLE, JENNIFER I

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/710,613	KHRIPACH ET AL.	
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4* is/are rejected.

7)☐ Claim(s) *9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-8 were pending and subject to and Election/Restriction Requirement. Claims 2-3 and 5-8 were canceled pursuant to Applicants' Response to the Election/Restriction Requirement, filed April 4, 2005. Claims 1, 4 and 9 are pending.

Request by the Examiner

2. The examiner noted that in the specification Applicants discusses brassinosteroid discovery as a class of plant hormones of steroid origin responsible for a wide spectrum of growth and adaptive reaction in plants footnoted by a book written by the inventors. However, no section of the book were included with the Information Disclosure Statement. The examiner has attempted to obtain a copy of the book to ascertain whether it is relevant to the examination of this patent application and has been unable to date to do so. She respectfully requests that if possible, Applicants review the publication and ascertain if any or all of the publication is relevant and if so provide a copy of any relevant portions to the Office with their next response.

Specification

3. The disclosure is objected to because of the following informalities: in [0013] to [0014] Applicants change the dosing range back and forth between 0.03-200 mcg/kg and 0/03-2 mcg/kg.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 deletes the daily doing range of 0.03-200 micrograms per kilogram of body weight. This deletion is not supported by the Specification and constitutes new matter.

Applicants specification discusses various ranges in conjunction with the method and of adminstering EBI and a pharmaceutical for an effective amount but does not support at least some language addressing at a minimum an effective amount. See [0013] by administering an effective amount, daily dose from about 0.03 to 200 mcg/kg of patient's body weight and more preferably 4-12 weeks in a daily amount of 0.03 to 2 mcg/kg, [0016] by administering a serum cholesterol lowering effective amount of 24-epibrassinolide, [0018] effective amount, [0019]-[0020] and entire patent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a plant hormone of structural formula I belong to brassinosteroid series" is vague and indefinite because there is no structural formula I either in the claim or anywhere in the Specification. Applicant is advised to delete this phrase.

Claim Objections

6. Claim 1 is objected to because of the following informalities: the parenthetical (EBI) is unnecessary, redundant and not used anywhere else in the claims. It is suggested that it be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winter, et al., Monitoring brassinosteroid biosynthetic enzymes by fluorescent tagging and HPLC analysis of their substrates and products, Phytochemistry, Vol. 51, (1999), 237-242 or H.G. Cutler, Advances in the Use of Brassinosteroids, ACs Symposium Series, 1994, vol. 551, pp. 85-102, in view of Rao, et al., Brassinosteroids – A new class of phytohormones, Current Science, Vol. 82, No. 10, pp. 1239-1245.

Winter discloses that 24-epibrassinolide has been detected in tomato cell suspension cultures. Abstract. Cutler discloses that 24-epibrassinolide has been detected in immature faba beans and its pollen. pp. 90 and 91. It is well known that individuals consume tomatoes and faba beans (broad beans) as part of a regular diet. Individuals are even known to consume immature tomatoes, i.e. green tomatoes as part of a normal diet. Rao discloses that 24-epibrassinolide is a biologically active brassinosteroid, being widely used in physiological studies and that young growing tissues contain higher levels of brassinosteroids than mature tissues and that immature seeds are the riches source with a range of 1-100ng. Per gm fresh weight, while shoots and

leaves usually have lower amounts, i.e. 0.01-0.1 ng pergm fresh weight. Pg. 1240. Thus the 24-epibrassinolide would still be present in the tomato and faba beans. Applicants own specification admits that as ubiquitous plant constituents characteristic for all plant species, brassinosteroids were, and are consumed by mammals with food throughout their evolution. [0012]. Thus, it would have been obvious to one of ordinary skill in the art to have administered the tomato or faba beans in the method to lower cholesterol, etc. because they are part of the normal diet and would have the same effect as they are being given in the same amount, i.e. no set amount over the same time period.

Allowable Subject Matter

9. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 9 is allowable because the amount of 24-epibrassinolide is administered as a medicament or a food supplement in such an amount that it would be next to impossible to eat in raw food. For example, a 110 pound female would need a minimum 1500 ng using even a .1ng/g amount for a faba bean or tomato and that is probably high considering Rao as mature plants have significantly less than immature plants, as set forth above, she would need to consume around nine cups of faba beans. See London, et al., The Versatile Grain and the Elegant Bean, A Celebration of the World Most Healthful Foods, Simon and Schuster, 1992, pg. 352. This ratio would hold true for any mammal.

The examiner notes that sterols are often hormones but there is no definitive evidence that phytosterols act in this capacity and the fact that phytosterols are well-known to lower

cholesterol and LDL in humans. Thus, the examiner did not make a 103 based upon the references cited below.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Jones, et al., Dietary phytosterols as cholesterol-lowering agents in humans, Canadian Journal of Physiology and Pharmacology, 1997, Vol. 75, pp. 217-227.

Matvienko, et al., A single daily does of soybean phytosterols in ground beef decreases serum total cholesterol and LDL cholesterol in young, mildly hypercholesterolemic men, American Journal of Clinical Nutrition, 2002, Vol. 76, pp. 57-64.

Maki, et al., Lip responses to plant sterol enriched reduced-fat spread incorporated into a National Cholesterol Education Program Step I diet, American Journal of Clinical Nutrition, 2001, Vol. 74, pp. 33-43.

Hendricks, et al., Spreads enriched with three different levels of vegetable oil sterols and the degree of cholesterol lowering in normocholerolaemic and mildly hypercholeserolaemic subjects, European Journal of Clinical Nutrition, 1999, Vol. 53, pp. 319-327.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer I. Harle
Examiner
Art Unit 1654

June 24, 2005